IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANDOZ INC. and RAREGEN, LLC *Plaintiffs*, v. UNITED THERAPEUTICS CORP. and SMITHS MEDICAL ASD, INC. *Defendants*.	Case No. 19-cv-10170-BRM-LHG **PLAINTIFFS' CLOSING STATEMENT IN SUPPORT OF PRELIMINARY INJUNCTION**

Plaintiffs Will Succeed on the Merits. The material facts are undisputed and confirm that Plaintiffs are likely to succeed on the merits:

1. Pumps and cartridges are not the same. This motion is only about ***cartridges*** because the unencumbered CADD MS-3 pumps outside of Defendants' control are durable and available to patients using Plaintiffs' drug. Mot. 5-6.

2. Prior to 2019, there were ***no restrictions*** on the use of ***cartridges*** by the specialty pharmacies, and the specialty pharmacies could purchase cartridges directly from Smiths. Donovan 43:1-11, 173:17-22 (there were no restrictions on the use of cartridges dispensed by Accredo prior to 2019); Benkowitz 26:8-19, 27:6-19 (same for CVS); Gencheff 250:12-23 (same for Accredo and CVS, as of December 2018).

3. In late 2018, Defendants learned Plaintiffs' entry was imminent and knew it threatened the Remodulin franchise. Ex. 459; Ex. 705 at #76. Only then did Defendants tell Accredo and CVS that they would be cut off from cartridges unless they agreed to only dispense cartridges to patients using Remodulin. Mot. 11–15.

4. To get access to cartridges and protect the severely ill patients Defendants were using as "negotiating leverage," the specialty pharmacies signed ***new agreements in April and May 2019*** that restricted their use of cartridges to only Remodulin. Ex. 725; Ex. 723. In addition, UTC and Smiths entered a new agreement in April 2019 that made UTC the sole purchaser of cartridges. As a result, the specialty pharmacies now must obtain cartridges from UTC instead of from Smiths and can only dispense the cartridges for Remodulin.

5. The restraints are not medically necessary. Defendants' sole purpose for them was "to prevent generic drug users" and "protect Remodulin from generic competition." Mot. 16–17.

6. These restraints block Plaintiffs from competing with Remodulin for subcutaneous patients and impair competition with Remodulin for intravenous patients. Mot. 17–19.

Defendants assert that, without the restraints, they "wouldn't have the

[cartridges] here today to fight over" because they "wouldn't have been produced." Tr. 32:7-19. But that is not true. UTC agreed to buy the cartridges in July 2017, ***two years before*** the restraints blocking competition existed, and six months ***after*** Smiths purchased enough resin to serve the entire market until at least 2025 (i.e., after cartridge supply had already expanded). Moreover, UTC bought the cartridges at Smith's regular prices, which other market participants (including Plaintiffs) would have accepted without any restraints. Walker 108:4-10.

Plaintiffs Will Suffer Irreparable Injury in the Absence of an Injunction. Plaintiffs have shown "that [they are] *more likely than not* to suffer irreparable harm in the absence of preliminary relief." *Reilly v. City of Harrisburg*, 858 F.3d 173, 179 (3d Cir. 2017) (emphasis added). First, Plaintiffs have suffered and will continue to suffer "loss of control of reputation, loss of trade, and loss of good will." *Opticians Ass'n v. Indep. Opticians*, 920 F. 2d 187, 195 (3d Cir. 1990); Rao Report, ECF 109, ¶ 104 (discussing harm to reputation and goodwill). Before the restraints and based on the availability of both cartridges and pumps, Plaintiffs promised the specialty pharmacies, payors, and prescribers that they would be able to serve all patients. Defendants blocked Plaintiffs from fulfilling that promise. But payors, prescribers and patients—which make the decisions to switch to generics (not the specialty pharmacies)—have no idea that Plaintiffs' inability to supply the market is because of Defendants. Even if they did, the primary concern of payors, prescribers,

and patients is whether a generic will be reliably available for use by the patient. To them, there is no difference between the uncertainty created by Plaintiffs' inability to reach subcutaneous patients and the supply issues that caused generic Flolan to fail. Ex. 1016 at 6; Ex. 1017 at 12; Jeffs 155:18-21, 163:6-164:7.

Second, the restraints have denied and continue to deny Plaintiffs some of the "unique, non-replicable business opportunity" inherent in their first-to-file rights. *See URL Pharma, Inc. v. Reckitt Benckiser Inc.*, 2016 WL 1592695, at *10 (E.D. Pa. Apr. 20, 2016) (finding irreparable harm where plaintiffs "denied" chance to "become the generic supplier" at "a time when there are few alternative providers"). The restraints are precluding Plaintiffs from maximizing their ability to penetrate the market and "attract subcutaneous patients," so Plaintiffs are losing the advantages of seeding the market as the first generic. *See* Rao Report, ¶ 104. And if Defendants block generic entry until UTC can switch patients to their new, proprietary pumps, then Plaintiffs will lose the benefit of "stickiness"—where patients choose to stay on generic—because Plaintiffs will have not yet had a chance to penetrate the market. *Id*. ¶ 103. That means Plaintiffs may never be able to quantify the full extent of their ongoing injury. *See Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharm. Co.*, 290 F.3d 578, 596 (3d Cir. 2002) ("[L]oss of market share is a potential harm which cannot be redressed . . . following a trial.").

Third, "irreparable damage exists here because of the high probability that

[RareGen and Sandoz] will cease to be an effective competitor in . . . product markets of vital interest to the nation's economy . . . ." *Grumman Corp. v. LTV Corp.*, 665 F.2d 10, 16 (2d Cir 1981). In the near future, Defendants' restraints will cause RareGen to lose employees and possibly abandon the market altogether. *See* Jeffs 195:12-196:7 (RareGen is already short on cash and treprostinil is its only product).

Defendants argue Plaintiffs should have fixed the problems caused by the secret restraints. But (1) the cartridge restraints did not exist until 2019; (2) Smiths told the specialty pharmacies in 2017 that cartridges would be available until 2025, Mot. 38; (3) until late 2018, the specialty pharmacies told Plaintiffs that they could access cartridges, Mot. 39; and (4) Smiths did not issue an end-of-life notice for cartridges until 2019, Mot. 13. Defendants hope to obscure these facts by conflating pumps and cartridges. But this motion has nothing to do with pumps—it is about cartridges. And only when Plaintiffs were poised to begin taking Defendants' business in 2019 did Defendants restrict cartridges and suppress competition.

Absent an Injunction, the Public Will Be Irreparably Harmed. "Consideration of the public interest is particularly appropriate in the context of a private antitrust suit where injunctive relief is sought." *Bascom Food Prod. Corp. v. Reese Finer Foods, Inc.*, 715 F. Supp. 616, 640 (D.N.J. 1989). If "the public interest [is] directly affected," this Court may "go much farther" in exercising its equitable powers than "when only private interests are involved." *Instant Air*

Freight Co. v. C.F. Air Freight, Inc., 882 F.2d 797, 803 (3d Cir. 1989). "This is especially the case where the public interest in question has been formalized in a statute," *id*., as it is here, in both the Hatch-Waxman Act and the federal antitrust laws. *See F.T.C. v. Actavis, Inc.*, 570 U.S. 136, 142 (2013) (Hatch-Waxman allows "the generic to piggyback on the pioneer's approval efforts, speeds the introduction of low-cost generic drugs to market," and "further[s] drug competition."); *Tasty Baking Co. v. Ralston Purina, Inc.*, 653 F. Supp. 1250, 1276 (E.D. Pa. 1987) (issuing preliminary injunction on competitor's antitrust claim based on "a compelling public interest in minimizing defendants' ability to extract monopoly profits"). Patients, payors, prescribers, and the public are hurt by Defendants' anticompetitive conduct.

Defendants Will Not Be Irreparably Injured by an Injunction. Defendants argue that the restraints are necessary to prevent a shortage of cartridges and serve "their patients." But there are enough cartridges available to serve *the entire market* until at least 2025. Mot. 34, 38. And for every patient who switches to generic treprostinil, Defendants will not need cartridges. That means Defendants will be able to serve all patients who choose Remodulin until 2025—with or without an injunction. UTC "will remain free to market and promote" Remodulin "so long as [consumers] are given the choice of whether or not to accept the product." *U.S. v. Microsoft Corp.*, 980 F. Supp. 537, 544 (D.D.C. 1997). Thus, the only "harm" facing Defendants comes from competition, and that harm should be disregarded.

Dated: December 17, 2019 Respectfully submitted,

By: */s/ Jenny Kramer*

ALSTON & BIRD LLP
Jenny Kramer (NJ Bar No. 014372001)
90 Park Avenue 15th Floor
New York, NY 10016
(212) 210-9400 (Phone)
Jenny.Kramer@alston.com
Michael P. Kenny (*pro hac vice*)
Matthew D. Kent (*pro hac vice*)
Allison S. Thompson (*pro hac vice*)
Jonathan D. Parente (*pro hac vice*)
1201 West Peachtree Street, Suite 4900
Atlanta, GA 30309
(404) 881-7000 (Phone)
Mike.Kenny@alston.com
Matthew.Kent@alston.com
Allison.Thompson@alston.com
Jonathan.Parente@alston.com

Attorneys for Plaintiff Sandoz Inc.

By: */s/ Thomas D. Pease*

QUINN EMANUEL URQUHART & SULLIVAN, LLP
Thomas D. Pease (NJ Bar No. 055421994)
Peter Calamari (*pro hac vice*)
51 Madison Avenue, 22nd Floor
New York, NY 10010
(212) 849-7000 (Phone)
thomaspease@quinnemanuel.com
petercalamari@quinnemanuel.com
Ethan C. Glass (*pro hac vice*)
Michael D. Bonanno (*pro hac vice*)
1300 I Street NW, Washington, DC 20005
(202) 538-8000 (Phone)
ethanglass@quinnemanuel.com
mikebonanno@quinnemanuel.com

Attorneys for Plaintiff RareGen, LLC